

### REMARKS

Applicants have amended 70 to specify a “first” reflective layer associated with the substrate, and that the active layer is “vertically aligned with” the reflective layer. Amended Claim 70 also recites “a second reflective layer covering at least a portion of said active layer.” Applicants have amended Claim 76 to specify that the cap portion is in “vertical alignment with said second reflective layer.” Applicants have amended Claim 78 to replace the phrase “chemically bound” with the phrase “immobilized through a reactive group” and to recite “a reflective layer covering at least a portion of said active layer.” Applicants have amended Claim 81 to specify that the cap portion is in vertical alignment with the reflective layer that covers at least a portion of the active layer. Applicants amended Claim 82 to specify that the reflective layer associated with the substrate is a second reflective layer. Applicants have amended Claim 84 to recite a second reflective layer covering at least a portion of the active layer. The amendments do not add new matter and are fully supported by the specification as filed. Support for the amendments to Claims 70 and 78 can be found, for example, at page 15, line 10 to page 16, line 4, at page 4, lines 17-20, Figures 14-17, and elsewhere throughout the specification.

Applicants have canceled Claim 77 without prejudice to, or disclaimer of, the subject matter contained therein. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the cancelled claim in this or any other patent application.

### Claim Objections

The Examiner has pointed out that in Applicants’ previous amendment, the phrase “associated with” was replaced by “adjacent to” in Claim 70, however, the phrase “associated with” was not crossed out. Applicants have amended Claim 70 to recite “in vertical alignment with.” The amendment reflects the changes made and Applicants respectfully request that the Examiner withdraw the objection accordingly.

### Rejection Under 35 U.S.C. § 112, first paragraph - Written Description

The Examiner has rejected Claims 78-83 as allegedly failing to comply with the written description requirement. Specifically, the Examiner states that Applicants’ recitation of the

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phrase “chemically bound” to the active layer in reference to the immobilization of DNA on the active layer is not described in the specification so as to convey to the skilled artisan that Applicants were in possession of the invention. Although not agreeing with the Examiner’s position, in order to advance prosecution of the case Applicants have amended Claim 78 to recite “immobilized through a reactive group.” Applicants refer the Examiner to the description of page 4, lines 17-20. Thus, Applicants respectfully request withdrawal of the rejection of Claims 78-83 under 35 U.S.C. § 112, first paragraph.

**Rejections Under 35 U.S.C. § 103(a)**

Applicants have the following comments with respect to the Office Action.

Claims 70-77 and 84

The Examiner has rejected Claims 70-77 and 84-86 under 35 U.S.C. § 103(a) as allegedly being obvious over of Sheppard et al. (U.S. Patent No. 6,143,247) in view of Wang et al. (U.S. Patent No. 5,922,617). The Examiner argues that Sheppard et al. disclose a bio-disc comprising a circular substrate, a reflective layer, a plurality of target zones disposed in the reflective layer, and an active layer adjacent to the reflective layer. According to the Examiner, the reflective layer includes an immobilized binding partner positioned to be contacted by an interrogation beam through the target zones. The Examiner asserts that Wang et al. disclose a circular bio-disk, a plurality of target zones disposed in the reflective layer and an active layer that includes chemically reactive groups for binding DNA to the active layer substrate. Applicants respectfully disagree.

To establish a *prima facie* case of obviousness a three-prong test must be met. First, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success found in the prior art. Third, the prior art must teach or suggest all of the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Sheppard et al. describe a disc for detecting particulate matter, such as cells. The disc described in Sheppard et al. has a surface detection chamber with transparent portions coated with specific binding reagent, and other portions coated with reflective material. In an alternative

format, the entire surface comprising the specific binding reagent is reflective. Sheppard et al. teach that the reflective regions and transparent regions can be engineered to comprise a pattern resembling or comprising a “bar code” for identification purposes, as well as to “provide[] a means for accomplishing tracking and focusing.” Col. 11, line 26 - Col. 12, line 14. Sheppard et al. do not describe a bio-disc with a second reflective layer as recited in the instant claims.

The Examiner maintains that Wang et al. “teach the second reflective portion . . . whereby analytes at the active sites are identified based on the information contained in the reflective header.” *Office Action* at 6. Applicants respectfully disagree. In fact, similar to Sheppard et al., the device taught in Wang et al. has a single reflective region, *i.e.*, header, that is associated with the substrate. The reflective layer in Wang et al. serves as a “bar code” to identify regions of the disc. As described in Col. 9, lines 3-17, the “headers” of Wang et al. are etched onto the solid substrate. Therefore, both Sheppard et al. and Wang et al. describe only a reflective surface associated with the substrate.

By contrast, as shown in Figure 5, and as discussed on page 16, lines 10-34 of the instant application, in addition to the reflective portion of the substrate, the claimed bio-disc comprises a cap portion with a reflective surface that covers at least a portion of the active layer, *in addition to* the reflective surface associated with the substrate, which comprises target zones. An interrogation beam is directed through the target zones present on the substrate and thereafter reflected from the reflective surface covering the substrate to form or contribute to the return beam. The return beam is then processed by a detector. Applicants teach that the reflective surface covering at least a portion of the active layer may be cover the entire active layer or alternatively only cover the portions of the active layer above the target zones as needed to reflect or return the interrogation beam that has passed through the target zone region. *See, e.g.*, page 29, lines 10-19.

The combination of Sheppard et al. and Wang et al. do not teach a bio-disk having a reflective layer associated with a substrate, and a second reflective layer associated that covers at least a portion of the active layer. Thus, the combination of Sheppard et al. and Wang et al. do not teach each and every limitation of the rejected claims. For this reason, the combination of these references would not make the rejected claims obvious to one of ordinary skill in the art. Accordingly, Applicants respectfully request withdrawal of this rejection.

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Claims 78-81 and 83

The Examiner has rejected Claims 78-81 and 83 under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over Curtis et al. (U.S. Patent No. 4,390,499) in view of Wang et al. According to the Examiner, Curtis discloses a device comprising a circular substrate (reference numeral **21** in Figure 3) and a plurality of flow channels associated with the substrate which are divided by break-away walls. The Examiner argues that while Curtis does not disclose DNA chemically bound to an active layer, it would have been obvious to the skilled artisan to apply the chemically bound DNA to the bio-disc of Wang et al. for the expected benefit of detecting high affinity interactions. Applicants respectfully disagree.

Applicants submit that there is no *prima facie* case of obviousness because the cited references, alone or in combination, do not teach or suggest all of the claim limitations. As an initial matter, Applicants disagree with the Examiner's assertion that Curtis discloses a device that comprises a "bio-disc" as alleged on page 8 of the Office Action. The Examiner points to the drive shaft identified in Figure 3 by reference numeral **21** as being a "circular substrate." However, Applicants note that reference numeral **21** in fact, refers to a drive shaft that drives the circular motion of a rotor **20**, that is configured to hold a "test package." The test packages described in Curtis et al. contain prepackaged reagents and an integral cuvette. Following the mixture of the reagents and sample, the final sample/reagent mix is directed to the cuvette, where the final mix is analyzed. Col. 3, lines 50-65. As such, Curtis et al. fail to teach a bio-disc for detecting the binding of target DNA to capture DNA comprising a substantially circular substrate configured to be read by an optical drive.

In the device described in Curtis et al., a combination of hydraulic, pneumatic and centrifugal forces causes breakage of rupturable seals of the test package that separate the prepackaged reagents, sample chamber, and cuvette of the test package. Col. 6, lines 12-17. Contrary to the Examiner's assertion, Curtis does not disclose a plurality of flow channels associated with a substantially circular substrate, wherein the flow channels are divided by a break-away retaining wall. Applicants note that the only "channels" associated with the alleged substrate **21** are tubes **37** that connect annular plenum chambers to provide pressure to rupture the seals of the prepackaged reagents. Col. 7, line 1 - Col. 8, line 9. Applicants also note that the seals within the "test chamber" of Curtis et al. are structured so that they require the use of

pneumatic pressure to rupture. Col. 7, line 44 - Col. 8, line 9. The device of Curtis requires a “means integral to [a] rotor for rupturing the breakable, sealed relationship between [a] sample compartment, [] reagent storage compartment and [] cuvette.” Curtis et al., Claim 1. Applicants’ bio-disc does not require such a structure. As such, Curtis does not teach or suggest the claimed invention to the skilled artisan.

Curtis et al. also fails to disclose DNA immobilized on an active layer associated with the flow channels. By contrast, the all of the reagents for the reactions assayed in Curtis et al. are in a fluid, and the final reaction mixture flows into a cuvette where it is assayed. Col. 10, lines 3-7. Therefore, Curtis et al. do not teach an active layer with an immobilized reagent, *e.g.*, DNA.

Further, Curtis et al. fails to disclose a reflective layer. Claims 78-81 and 83 each recite a reflective layer covering at least a portion of the active layer. Because Curtis et al. does not teach or suggest a reflective layer, it does not teach or suggest each and every limitation of the rejected claims.

The teachings of Wang et al. do not cure the defects of Curtis et al. Specifically, Wang et al. also do not disclose a plurality of flow channels associated with the substrate which are divided by break-away walls. In fact, Wang et al. do not describe flow channels at all. Rather, Wang et al. describe compact discs with immobilized reagents printed to their surface. In contrast to Applicants’ claimed invention, in which flow channels permit contact between substrate and reagents, the surface of the compact discs of Wang et al. are contacted directly with a solution containing a component to be tested. Col. 9, lines 26-55. Wang et al. also does not teach or suggest a reflective layer covering at least a portion of the active layer. As discussed above, Wang et al. merely teach a reflective header that etched onto the solid substrate. The reflective layer in Wang et al. serves as a “bar code” to identify regions of the disc.

As demonstrated above, the combination of Curtis et al. and Wang et al. do not teach or suggest all of the claim limitations of Claims 78-81 and 83, and therefore do not support a *prima facie* case of obviousness. Applicants respectfully request that the Examiner withdraw the rejection.

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#### Claim 84

The Examiner has rejected Claim 84 under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over Curtis et al. in view of Wang et al. and Sheppard et al. The Examiner's assessment of the teachings of Wang et al. and Sheppard et al. are described above. According to the Examiner, Sheppard et al. teach a bio-disc with channels connected by valves that require the application of pressure (via rotation of the disc) to induce fluid to flow from the channels. According to the Examiner, this suggests "break away retaining" as recited in Claim 84.

Amended Claim 84 recites a cap layer, and a reflective layer that covers at least a portion of the active layer of the bio-disc. As discussed above, neither Sheppard et al. nor Wang et al. disclose such a reflective layer. Curtis et al. also do not teach this reflective layer, thus the references, when taken alone or in combination, do not disclose each and every element of the claims, and cannot support a *prima facie* case of obviousness under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the rejection accordingly.

#### **Rejection Under Judicially Created Doctrine of Obviousness Type Double Patenting**

The Examiner has provisionally rejected Claims 77-78 on the ground of nonstatutory obviousness-type double patenting over Claims 6-8, 10-11 and 137-145 of co-pending U.S. Patent Application No. 10/194,396. Applicant will address this rejection, for example, by filing a terminal disclaimer, when the instant claims are allowed and no other rejections remain.

#### **CONCLUSION**

Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefore, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a

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telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

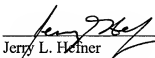
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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